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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,477	01/18/2002	Michael C. Stewart	80121-05730	5572

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EXAMINER
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KASZTEJNA, MATTHEW JOHN

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/054,477	<b>Applicant(s)</b> STEWART ET AL	
	<b>Examiner</b> Matthew J. Kasztejna	<b>Art Unit</b> 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2005.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 84,85,88-100 and 103-115 is/are pending in the application.
- 4a) Of the above claim(s) 86,87,101 and 102 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 84,85,88-100 and 103-115 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/3/03</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-17, 42, 43-53, 57-63 and 80-83, in the reply filed on June 9, 2005 is acknowledged. Claims 18-41, 53-56 and 64-79 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Groups II, III and IV, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 9, 2005.

Furthermore, applicant's election without traverse of Species A, claims 84-85, 88-100 and 103-115, in the reply filed on June 9, 2005 is acknowledged. Claims 86-87 and 101-102 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species C and D, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 9, 2005.

The requirement is still deemed proper and is therefore made FINAL.

### ***Drawings***

The drawings are objected to because of the poor quality of the figures. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes

made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 84 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent No. 5,707,382 to Sierocuk et al.

**In regards to claims 84, 99 and 103-104**, Sierocuk et al. disclose a tissue dissector comprising: an elongated tube 17 having a proximal end and a distal end and enclosing endoscopic imaging fibers 12; and a dissecting, viewing and dilating unit removably mounted on the tubular body distal end, including; a transparent distal tip 24 having tapered outer walls converging to a blunt end for dissecting tissue, the tip being disposed on a distal end of the dilating unit to dissect tissue and facilitate passage of the tubular body through tissue under endoscopic visualization (see Col. 2, Lines 30-35); and a dilating element 15 having an exterior contour that gradually increase in size

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in the proximal direction from a distal edge thereof until a maximum cross-sectional dimension greater than the cross-sectional dimension of the distal end of the tubular body, the dilating element then decreasing in size to a proximal edge, the gradual size increase and decrease therefore facilitating atraumatic expansion of tissue following dissection by the tapered distal tip (see Fig. 1 and Col. 4, Lines 20-52).

**In regards to claims 88-92 and 105-109**, Sierocuk et al. disclose a tissue dissector, wherein exterior contour of the dilating element is an oval-shape (see Fig. 1). Furthermore, Sierocuk et al. teaches that although the dilating unit 15 is illustrated as a spherical balloon, other desired shapes can be used, and the shape of the balloon is not an essential feature of the invention.

**In regards to claims 93-94 and 110-111**, Sierocuk et al. disclose a tissue dissector, wherein the cross-sectional dimension of the dilating element is at least two times larger than the cross-sectional dimension of the distal end of the tubular body (see Fig. 2).

**In regards to claims 95 and 112**, Sierocuk et al. disclose a tissue dissector, wherein the dilating element is inherently compressible as it is an inflatable balloon (see Col. 3, Lines 50-61).

**In regards to claims 96-97 and 113-114**, Sierocuk et al. disclose a tissue dissector, wherein the tubular body is an endoscope 12 (see Col. 4, Lines 51-60).

**In regards to claims 98 and 115**, Sierocuk et al. disclose a tissue dissector, wherein the tubular body is a cannula 17 having a lumen, the endoscopic imaging fibers being provided within an endoscope that fits within the cannula lumen and includes a

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fitting near its proximal end adapted to couple to a viewing camera (see Fig. 1 and Col. 4, Lines 56-60).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 85 and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,707,382 to Sierocuk et al. in view of U.S. Patent No. 5,725,479 to Knight et al.

**In regards to claims 85 and 100**, Sierocuk et al. disclose a tissue dissector having a removable dilating unit attached to the distal end of the flexible tube but are silent with respect to screw threads positioned on an outer surface of the tubular body near the distal end thereof, and wherein the dilating unit further comprises a threaded bore hole for engaging the length of screw threads and mounting the dilating unit on the distal end of the tubular body. Knight et al. teach of an analogous medical apparatus wherein the working head 16 is threaded onto securing means 11 about the distal end of an endoscope (see Fig. 16 and Col. 7, Lines 1-20). It would have been obvious to one skilled in the art at the time the invention was made to secure the dilating end to the flexible tube in the apparatus of Sierocuk et al. via screw threads to ensure a secure connection which can only be removed by unthreading as taught by Knight et al.


**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Kasztejna whose telephone number is (571) 272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MJK *mk*  
9/28/05

  
BEVERLY M. FLANAGAN  
PRIMARY EXAMINER